

Effectiveness and cost-effectiveness study of the Liaison Mental Health-Education Program for schools

Submission date 29/05/2024	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/06/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/06/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Schools play a crucial role in the development of children and adolescents. Mental health prevention and intervention programs in schools can serve as tools for early detection and management of mental health issues among students. This study aims to evaluate the effectiveness and cost-effectiveness of a mental health prevention, promotion, and intervention program implemented in various schools in the Community of Madrid (Comunidad de Madrid), Spain. It involves a community child and adolescent mental health resource for coordination and liaison between educational centers and child and adolescent mental health services in the healthcare area of Hospital G.U. Gregorio Marañón and Hospital U. del Sureste, in Comunidad de Madrid. Each clinical team includes a psychiatrist, a child and adolescent clinical psychologist, and a mental health specialized nurse.

Who can participate?

All students from schools (public and private) in the districts of Retiro, Moratalaz, Vicálvaro, Rivas-Vaciamadrid, and Arganda del Rey (Madrid, Spain) where the mental health coordination and liaison program has been implemented will be invited to participate, as well as students from control schools. Additionally, parents of these students and teachers from participating schools will be offered participation. For the research study on the effectiveness of clinical sub-programs, all children and adolescents included in these sub-programs, who agree to participate and provide informed consent, will be included.

What does the study involve?

All students from participating schools will be informed about the study. Individuals who agree to participate and provide informed consent will be assessed at the start of the study and after 6, 12, and 24 months. For the effectiveness study of clinical sub-programs, participation will be offered to all students included in these sub-programs. Recruitment, assessment, data collection, and follow-up will be conducted by healthcare professionals from the liaison program. Throughout the 12-month follow-up period for each case in the clinical sub-programs effectiveness study, information related to program accessibility, effectiveness indicators, and efficiency will be collected. The evaluation will involve the application of clinical scales (self and

hetero-administered) and the collection of information on program implementation costs and academic data such as absenteeism or disciplinary measures.

What are the possible benefits and risks of participating?

There are no risks associated with participating in this study. Participation will not result in direct benefits. Participants will be contributing to a better understanding of the effects of a mental health prevention and promotion program for children and adolescents.

Where is the study run from?

Hospital General Universitario Gregorio Marañón (Spain)

When is the study starting and how long is it expected to run for?

October 2023 to November 2026

Who is funding the study?

1. Fundación Alicia Koplowitz (Spain)

2. Fundación Nemesio Díez (Spain)

Who is the main contact?

Dr Celso Arango López, carango@hggm.es

Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil Known

Secondary identifying numbers

PSY-SCHOOL 1.0

Study information

Scientific Title

Effectiveness and cost-effectiveness study of the Coordination and Liaison Child and Adolescent Mental Health Program for schools

Acronym

PSY-SCHOOL

Study objectives

The mental health coordination and liaison program for schools will constitute an effective and cost-effective intervention. Patients included in the clinical subprograms will present, 12 months after the inclusion in the program, or upon being discharged from it, an improvement in their overall functionality, in their quality of life and a lesser severity on their psychopathology.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 22/01/2024, Ethics committee of research with medicines Hospital General Universitario Gregorio Marañón (C/ Dr. Esquerdo 46, Pabellón de Gobierno, Primera Planta, Madrid, 28007, Spain; +34 (0)91 586 7007/91 or +34 (0)91 426 9378; ceim.hgugm@salud.madrid.org), ref: PSY-SCHOOL

Study design

Observational prospective longitudinal study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Community, School

Study type(s)

Other, Efficacy

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Child and adolescent mental health disorders

Interventions

All students from schools (public and private) in the districts of Retiro, Moratalaz, Vicálvaro, Rivas-Vaciamadrid, and Arganda del Rey (Madrid, Spain), where the mental health coordination and liaison program has been implemented, will be invited to participate, as well as students from control schools. Additionally, parents of these students and teachers from participating schools will be offered participation. Individuals who agree to participate and provide informed consent will be assessed at baseline and 6, 12, and 24 months from the start of the study. The evaluation will involve the application of questionnaires and scales (self and hetero-administered) and the collection of information on program implementation costs and academic data such as absenteeism or disciplinary measures.

For the effectiveness study of the clinical sub-programs (the clinical assessment subprogram and the coordination subprograms that provide case-management/coordination for the students with a diagnosed mental health condition, attending a public mental health resource), all children and adolescents included in these sub-programs, who agree to participate and provide informed consent will be included. For this part of the study, recruitment, assessment, data collection, and follow-up will be conducted by healthcare professionals from the liaison program; throughout a 12-month follow-up period. For each case in the clinical sub-programs effectiveness study, information related to program accessibility, effectiveness indicators, and efficiency will also be collected. The evaluation will involve the application of clinical scales (self and hetero-administered) and also the collection of information on program implementation costs and academic data such as absenteeism or disciplinary measures.

Intervention Type

Other

Primary outcome measure

1. Cost-effectiveness of the program will be evaluated by measuring:
 - 1.1. Behavioural and emotional difficulties of the participants measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline, 6, 12 and 24 months of follow-up
 - 1.2. Health-related quality of life of children and adolescents measured using the EQ-5D-Y at baseline, 6, 12 and 24 months of follow-up
 - 1.3. Mental well-being measured in parents and teachers using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline, 6, 12 and 24 months of follow-up
 - 1.4. Impact of the program on the educational system measured by extracting information from school records (e.g., academic performance, school absenteeism, number of cases of bullying) at baseline, 6, 12 and 24 months of follow-up
 - 1.5. Direct and indirect healthcare and social costs of the program, measured using short questionnaires ad hoc, as well as extracting information from school records, at baseline, 6, 12 and 24 months of follow-up
 - 1.6. Direct implementation costs of the program (e.g., clinicians salaries)
2. Effectiveness of the clinical sub-programs is evaluated with the following variables and measures:
 - 2.1. Overall functionality (in children and adolescents) measured using the Children's Global Assessment Scale (CGAS) at baseline, 6 and 12 months of follow-up.
 - 2.2. Severity of the psychopathology (in children and adolescents) measured using the Clinical Global Impressions-Severity (CGI-S) at baseline, 6 and 12 months of follow-up.
 - 2.3. Improvement of the psychopathology (in children and adolescents) measured using the CGI-I at 6 and 12 months of follow-up.
 - 2.4. Specific psychopathological symptoms (in children and adolescents) measured using specific clinical scales (such as the Hamilton Depression Rating Scale [HDRS], Positive and Negative

Syndrome Scale [PANSS]), according to clinician criteria, at baseline, 6 and 12 months of follow-up.

2.5. Health-related quality of life of children and adolescents measured using the EQ-5D-Y at baseline, 6 and 12 months.

Secondary outcome measures

1. Satisfaction with the Mental Health Clinical Liaison Program, measured in teachers and clinicians (from other mental health services where participants are attended), using a self-device questionnaire, based on the general satisfaction questionnaire administered in other programs/services at the Gregorio Marañón Hospital at 12 months of follow-up or after the patient has been discharged.

2. Accessibility measured using the following indicators at baseline:

2.1. Response time (measured in hours/days): the time difference between the patient referral date and the date the patient is included in the subprogram

2.2. Origin of referral

2.3. Acceptance of referral

3. Efficiency measured using the following indicators after 12 months of follow-up (or after the patient has been discharged):

3.1. Number of discharges

3.2. Average length of stay in the subprogram

3.3. Number of visits per clinician

3.4. Referrals to other public mental health services (such as the community mental health centre)

Overall study start date

01/10/2023

Completion date

30/11/2026

Eligibility

Key inclusion criteria

1. All students (age 3 to 19 years) from schools (public and private) in the districts of Retiro, Moratalaz, Vicálvaro, Rivas-Vaciamadrid, and Arganda del Rey (Madrid, Spain) where the mental health coordination and liaison program has been implemented, as well as students from the control schools selected. Parents of these students and teachers from participating schools, as well as from control schools.

2. For the part of the study on the effectiveness of the clinical sub-programs, all students (aged 3 to 19 years) from schools (public and private) where the mental health coordination and liaison program has been implemented, and that are included in these sub-programs. Parents of these students.

3. Informed consent provided by students, parents and teachers.

Participant type(s)

Patient, Learner/student, Other

Age group

Child

Lower age limit

3 Years

Upper age limit

19 Years

Sex

Both

Target number of participants

15000

Key exclusion criteria

None

Date of first enrolment

15/05/2024

Date of final enrolment

30/07/2026

Locations

Countries of recruitment

Spain

Study participating centre

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Sponsor information

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Sponsor type

Hospital/treatment centre

Website

<https://www.comunidad.madrid/hospital/gregoriomaranon/profesionales/instituto-psiquiatria-salud-mental>

Funder(s)

Funder type

Charity

Funder Name

Fundación Alicia Koplowitz

Alternative Name(s)

Alicia Koplowitz Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Spain

Funder Name

Fundación Nemesio Díaz

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

30/05/2027

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available upon request from Dr Celso Arango (carango@hggm.es).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0		06/06/2024	No	Yes
Participant information sheet	version 1.0		06/06/2024	No	Yes
Participant information sheet	version 1.0		06/06/2024	No	Yes
Participant information sheet	version 1.0		06/06/2024	No	Yes
Participant information sheet	version 1		06/06/2024	No	Yes